

82W 1635

PTO/SB/21 (09-04)  
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	08/480,472	
	Filing Date	June 6, 1995	
	First Named Inventor	Sherrol McDonough	
	Art Unit	1635	
	Examiner Name	Marschel, A.	
Total Number of Pages in This Submission	43	Attorney Docket Number	GP034-03.DV1

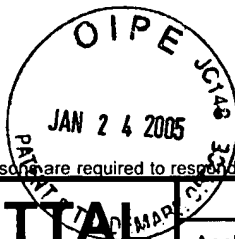
ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input checked="" type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	2 Copies of Cited References (24 pgs.);
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	Form PTO/SB/08 in duplicate (8 pgs.); and
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s) _____	Form PTO-1449 in duplicate (6 pgs.).
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	Gen-Probe Incorporated		
Signature			
Printed name	Charles B. Cappellari		
Date	January 19, 2005	Reg. No.	40,937

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:			
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Typed or printed name	Charles B. Cappellari	Date	January 19, 2005

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PTO/SB/17 (10-04)

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# FEE TRANSMITTAL

## for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$ 180.00)

**Complete if Known**

Application Number	08/480,472
Filing Date	June 6, 1995
First Named Inventor	Sherrol McDonough
Examiner Name	Marschel, A.
Art Unit	1631
Attorney Docket No.	GP034-03.DV1

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit Account Number  
Deposit Account Name

07-0835

Gen-Probe Incorporated

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 790	2001 395	Utility filing fee	
1002 350	2002 175	Design filing fee	
1003 550	2003 275	Plant filing fee	
1004 790	2004 395	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 88	2201 44	Independent claims in excess of 3
1203 300	2203 150	Multiple dependent claim, if not paid
1204 88	2204 44	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION** (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 430	2252 215	Extension for reply within second month	
1253 980	2253 490	Extension for reply within third month	
1254 1,530	2254 765	Extension for reply within fourth month	
1255 2,080	2255 1,040	Extension for reply within fifth month	
1401 340	2401 170	Notice of Appeal	
1402 340	2402 170	Filing a brief in support of an appeal	
1403 300	2403 150	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,370	2501 685	Utility issue fee (or reissue)	
1502 490	2502 245	Design issue fee	
1503 660	2503 330	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	180.00
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 790	2809 395	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 790	2810 395	For each additional invention to be examined (37 CFR 1.129(b))	
1801 790	2801 395	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 180.00)

**SUBMITTED BY**

(Complete if applicable)

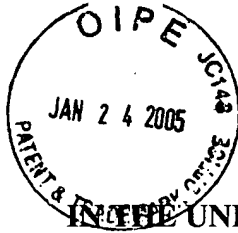
Name (Print/Type)	Charles B. Cappellari	Registration No. (Attorney/Agent)	40,937	Telephone	858 410-8927
Signature		Date	January 19, 2005		

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:	)	Group Art Unit: 1631
	)	
McDONOUGH <i>et al.</i>	)	Examiner: Marschel, A.
	)	
Serial No. 08/480,472	)	Atty. Docket No. GP034-03.DV1
	)	
Filed: June 6, 1995	)	Confirmation No. 9286
	)	
For: NUCLEIC ACID SEQUENCE	)	
AMPLIFICATION	)	

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97(c)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants bring to the Examiner's attention the references listed on the enclosed Form PTO/SB/08 and Form PTO-1449 from sister application Serial No. 08/479,105 (two copies of each) for consideration in connection with the examination of the above-identified application. A copy of each identified reference which was not previously cited during the prosecution of ancestor application Serial Nos. 07/855,732 and 08/345,861 is enclosed herewith.

This Information Disclosure Statement is being submitted under 37 C.F.R. § 1.97(c) more than three months from the filing date of the instant application and after the mailing date of a first Office action on the merits but before the mailing date of either a final action or notice of allowance.

Please charge the fee due under 37 C.F.R. § 1.17(p) to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

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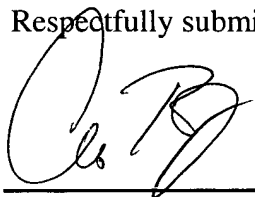
Serial No. 08/480,472  
Atty. Docket No. GP034-03.DV1

Applicants respectfully request that the Examiner indicate consideration of the cited references by returning copies of the enclosed Forms PTO/SB/08 and PTO-1449 with the Examiner's initials or other appropriate marks.

**Certificate of Mailing**

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being deposited on the date indicated below with the U.S. Postal Service as first class mail addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Respectfully submitted,



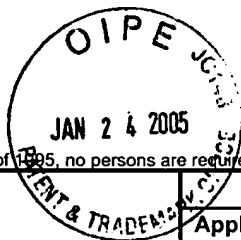
Dated: January 19, 2005

By:

\_\_\_\_\_  
Charles B. Cappellari  
Registration No. 40,937  
Attorney for Applicants

GEN-PROBE INCORPORATED  
Patent Department  
10210 Genetic Center Drive  
San Diego, California 92121  
PH: (858) 410-8927  
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PTO/SB/08B (08-03)

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Substitute for form 1449/PTO

**Complete if Known****INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Application Number	08/480,472
Filing Date	June 6, 1995
First Named Inventor	Sherrol McDonough
Art Unit	1631
Examiner Name	Marschel, A.
Attorney Docket Number	GP034-03.DV1

Sheet

2

of

4

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Brewer, et al., "Mechanistic Independence of Avian Myeloblastosis Virus DNA Polymerase and Ribonuclease H," Dec. 1974, J. Virol., 14(6):1494-1502, ASM, USA.	
		Champoux, et al., "Mechanism of RNA Primer Removal by the RNase H Activity of Avian Myeloblastosis Virus Reverse Transcriptase," Mar. 1984, J. Virol., 49(3):686-691, ASM, USA.	
		Collett, et al., "In Vitro Transcription of 70S RNA by the RNA-Directed DNA Polymerase of Rouse Sarcoma Virus: Lack of Influence by RNase H," Jan. 1976, J. Virol. 17(1):291-5, PMID: 54443, ASM, USA.	
		Crouch, R.J., "Ribonuclease H: from discovery to 3D structure," Sep. 1990, New Biol., 2(9):771-7, PMID: 2177653.	
		Day, R., "How to Write and Publish a Scientific Paper," 2nd Ed., Philadelphia: ISI Press, 1983, p.170.	
		Fahy, et al., "Self-sustained sequence replication (3SR): an isothermal transcription-based amplification system alternative to PCR," Aug. 1991, PCR Methods Appl., 1(1):25-33, PMID: 1842917.	
		Grandgenett, et al., "Different Mode of Action of Ribonuclease H in Purified alpha and alpha beta Ribonucleic Acid-Directed Deoxyribonucleic Acid Polymerase from Avian Myeloblastosis Virus" Aug. 25, 1974, J. Biol. Chem., 249(16):5148-5152, USA.	
		Kacian, et. al., "Synthesis of extensive, possibly complete, DNA copies of poliovirus RNA in high yields and at high specific activities," July 1976, Proc. Natl. Acad. Sci., 73(7):2191-2195, USA.	
		Kacian, et al., "Anticomplementary nature of smaller DNA produced during synthesis of extensive DNA copies of poliovirus RNA," October 1976, Proc. Natl. Acad. Sci., 73(10):3408-3412, USA.	
		Keller, et al., "Degradation of DNA RNA Hybrids by Ribonuclease H and DNA Polymerase of Cellular and Viral Origin," November 1972, Proc. Natl. Acad. Sci. 69(11):3360-3364, USA.	

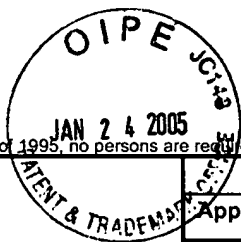
Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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**Complete if Known****INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 3

of

4

Application Number 08/480,472

Filing Date June 6, 1995

First Named Inventor Sherrol McDonough

Art Unit 1631

Examiner Name Marschel, A.

Attorney Docket Number GP034-03.DV1

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Maniatis, et al., Molecular Cloning, 1982, Cold Spring Harbor, N.Y.: Cold Spring Harbor Press, pp. 128, 213-214.	
		Marcus, et al., "Reverse Transcriptase-Associated RNase H Activity II. Inhibition by Natural and Synthetic RNA," Sept. 1978, J. Virol. 27(3):576-581, ASM, USA.	
		Modak, et al., "Specific Inhibition of DNA Polymerase-Associated RNase H by DNA," Apr. 1977, J. Virol., 22(1):243-246, ASM, USA.	
		Moelling, K., "Characterization of reverse transcriptase and RNase H from friend-murine leukemia virus," Nov. 1974, Virology, 62(1):46-59, PMID: 4138103.	
		Myers, et al., "RNA primer used in synthesis of anticomplementary DNA by reverse transcriptase of avian myeloblastosis virus," March 1980, Proc. Natl. Acad. Sci., 77(3) 1316-1320, USA.	
		Myers, et al., "Sodium pyrophosphate inhibition of RNA-DNA hybrid degradation by reverse transcriptase," Nov. 1978, Proc. Natl. Acad. Sci., 75(11):5329-5333, USA.	
		Myers, et al., "Synthesis of full-length DNA copies of avian myeloblastosis virus RNA in high yields," July 1977, Proc. Natl. Acad. Sci., 74(7):2840-2843, USA.	
		Resnick, et al., "Involvement of Retrovirus Reverse Transcriptase-Associated RNase H in Initiation of Strong Stop (+) DNA Synthesis and the Generation of the Long Terminal Repeat," Sept. 1984, J. Virol. 51(3):813-821, ASM, USA.	
		Rogall, et al., "Differentiation of Mycobacterium species by direct sequencing of amplified DNA," Sept. 1990, J. Gen. Microbiol., 136(Pt. 9):1915-1920, PMID: 2283506.	
		Srivastava, et al., "Reverse transcriptase-associated RNase H. Part IV. Pyrophosphate does not inhibit RNase H activity of AMV DNA polymerase," Dec. 14, 1979, Biochem. Biophys. Res. Commun., 91(3):892-899, PMID: 93479.	

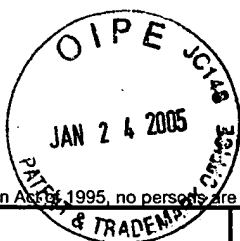
Examiner Signature		Date Considered	
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Examiner Name	Marschel, A.
Attorney Docket Number	GP034-03.DV1

Sheet

4

of

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		Wintersberger, U., "Ribonucleases H of retroviral and cellular origin," 1990, Pharmacol. Ther., 48(2):259-280 PMID: 1963496.	
		Wohrl, et al., "Mutations of a conserved residue within HIV-1 ribonuclease H affect its exo- and endonuclease activities," Aug. 5, 1991, J. Mol. Biol., 220(3):801-818, PMID: 1714505.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.  
213/067SERIAL NO.  
08/479,105APPLICANT:  
Diane L. McAllister et al.FILING DATE:  
June 6, 1995

GROUP:

Citations for Divisional Application  
Serial No. 08/480,472, Filed June 6, 1995  
Attorney Docket No. GP034-03.DV1  
Page 1 of 3

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE
AA	4 6 8 3 2 0 2	07/28/87	Mullis			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION YES NO
AB	9 1 0 1 3 8 4	07.02.91	PCT/WO (Kacian and Fultz)			
AC	0 4 0 8 2 9 5	16.01.91	EPO (Kacian and Fultz)			
AD	0 4 3 9 1 8 2	25.01.91	EPO (Backman et al.)			
AE	9 2 0 7 9 5 7	14.05.92	EPO (Cimino et al.)			
AF	9 2 2 2 6 6 3	23.12.92	WO/PCT (Schuster and Beminger)			
AG	0 5 8 7 2 6 6	06.05.93	EPO (Kacian et al.)			
AH	5 5 9 7 0 9	24.02.88	Canada (Malek and Davey)			
AI	0 3 2 9 8 8 2	30.08.89	EPO (Davey and Malek)			
AJ	0 3 7 3 9 6 0	20.07.90	EPO (Gingeras)			
AK	8 7 0 6 2 7 0	22.10.87	WO/PCT (Chu et al.)			
AL	8 9 0 1 0 5 0	09.02.89	WO/PCT (Burg et al.)			
AM	9 0 1 4 4 3 9	29.11.90	WO/PCT (Kramer and Lizardi)			
AN	0 3 0 0 7 9 6	25.01.89	EPO (Becker et al.)			
AO	8 8 1 0 3 1 5	29.12.88	WO/PCT (Gineras et al.)			
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AQ	2 6 5 9 0 8 6	02.03.90	France (Brisson-Noel)			
AR	2 6 5 1 5 0 5	06.09.89	France (Guesdon et al.)			
AS	9 1 1 5 6 0 1	04.04.91	WO/PCT (Shuldiner and Roth)			
AT	0 3 9 8 6 7 7	16.05.90	EPO (Wirth and Patel)			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Bethesda Research Laboratories Catalogue and Reference Guide, Bethesda Research Laboratories, Bethesda, MD (1988) p. 37
AB	Both et al., "A general strategy for cloning double-stranded RNA: nucleotide sequence of the Simian-11 rotavirus gene 8," <u>Nucleic Acids Research</u> 10:7075 (1982)
AC	Cashdollar et al., "Cloning the Double-stranded RNA Genes of a Reovirus: Sequence of the cloned S2 gene," <u>Proc. Natl. Acad. Sci. USA</u> 79:7644-7648 (1982)

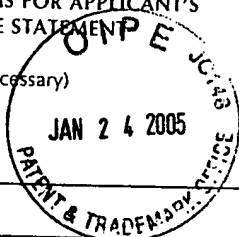
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08/479,105LIST OF PATENTS AND OTHER ITEMS FOR APPLICANT'S  
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APPLICANT:  
Diane L. McAllister et al.FILING DATE:  
June 6, 1995

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Serial No. 08/480,472, Filed June 6, 1995  
Attorney Docket No. GP034-03.DV1  
Page 2 of 3

AD	Cox et al., "The 16S ribosomal RNA of <i>Mycobacterium leprae</i> contains a unique sequence which can be used for identification by the polymerase chain reaction," <u>J. Med. Microbiol.</u> , 35:284-290 (1991)
AE	European Search Report for Application No. 90307503.4 dated 7/21/91
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AG	Grachev et al., "Oligonucleotides complementary to a promoter over the region -8... +2 as transcription primers for <i>E. coli</i> RNA polymerase," <u>Nucleic Acids Research</u> 12:8509 (1984)
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AI	Gubler, <u>Guide to Molecular Cloning Techniques</u> , Academic Press, NY, NY (1987) p. 330
AJ	Hayes, "The Genetics of Bacteria and their Viruses," John Wiley & Sons Inc., 2nd ed.:239-257, New York (1964)
AK	Joyce, "Amplification, Mutation and Selection of Catalytic RNA," <u>Gene</u> , 82:83-87 (1989)
AL	Khorana, "Total Synthesis of a Gene," <u>Science</u> , 203:614-25 (1979)
AM	Krug and Berger, "Ribonuclease H activities associated with viral reverse transcriptases are endonucleases," <u>Proc. Natl. Acad. Sci. USA</u> 86:3539-3543 (1989)
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AO	Kupper et al., "Promoter-dependent transcription of TRNA <sub>1</sub> genes using DNA fragments produced by restriction enzymes," <u>Proc. Natl. Acad. Sci. USA</u> 72:4754 (1975)
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AR	Lomonosoff, et al., "The Location of the First AUG Codons in Cowpea Mosaic Virus RNAs," <u>Nucleic Acids Research</u> , 10,16:4861-72 (1982)
AS	Lowary et al., "A Better Way to Make RNA for Physical Studies," <u>Structure &amp; Dynamics of RNA</u> , Nato ASI Series Knippenberg, eds. (New York: Plenum Press, 1986) Vol. 110
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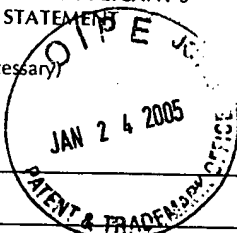
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AZ	Stent, "Molecular Biology of Bacterial Viruses," W.H. Freeman & Company, 157-63, San Francisco (1963)
BA	Tyagi et al., <u>Trop. Med. Parasitol.</u> 41:294-296 (1990)
BB	Watson and Crick, "Molecular Structure of Nucleic Acids," <u>Nature</u> , April 25, 1953, p. 737
BC	Watson & Crick, "Genetical Implications of the Structure of Deoxyribonucleic Acid," <u>Nature</u> , 171:964-967 (1953)
BD	Wilk et al., "Backbone-modified oligonucleotides containing a butaneodiol-1,3 moiety as a 'vicarious segment' for the deoxyribosyl moiety - synthesis and enzyme studies," <u>Nucleic Acids Research</u> 18:2065-2068 (1990)
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